

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 09/546,573 Confirmation No.: 3408
Applicant : Mads HOLTEN-ANDERSEN et al.
Filed : April 10, 2000
Title : TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES
TYPE-1 (TIMP-1) AS A CANCER MARKER
TC/Art Unit : 1642
Examiner: : Stephen L. Rawlings, Ph. D.

Docket No. : 59866.000002
Customer No. : 21967

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants submit attached Form PTO-SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office in the above-captioned application.

Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

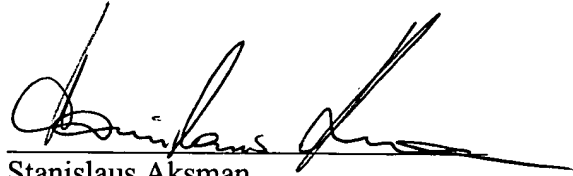
For the convenience of the Examiner in considering the cited references, a copy of each of the cited references is enclosed with this communication. In considering the cited references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited references obtained by the associated individuals, or were made thereon during the study of the

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: November 2, 2004

By:

A handwritten signature in black ink, appearing to read 'Stanislaus Aksman', written over a horizontal line.

Stanislaus Aksman

Registration No. 28,562

Hunton & Williams LLP
Intellectual Property Department
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Washington, DC 20006
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)
SA/sdw

references by the associated individuals. Applicants respectfully point out that the submission of the listed references in this Supplemental Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Supplemental Information Disclosure Statement is not an indication that a search has been made by Applicants.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(c), this Supplemental Information Disclosure Statement is being filed (i) before the mailing date of a final Office Action for the above-identified patent application; (ii) before the mailing date of a Notice of Allowance for the above-identified patent application; or (iii) before the mailing date of an Office Action that otherwise closes prosecution in the above-identified patent application. Accordingly, this Supplemental Information Disclosure Statement is accompanied by a statement under 37 C.F.R. § 1.97(e).

The undersigned hereby states under 37 C.F.R. § 1.97(e)(2) that no item of information contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, after making reasonable inquiry, no item of information contained in this Supplemental Information Disclosure Statement was known to any individual associated with the filing and prosecution of the above-identified patent application more than three months prior to the filing of this Supplemental Information Disclosure Statement.

However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

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|---|--|--|--|--|--|---------------------------------------|--|
| FORM PTO-1449 (REV. 7-80) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: 59866.000002 | | SERIAL NUMBER: 09/546,573 | |
| LIST OF MATERIALS CITED BY APPLICANT (Use several sheets if necessary) Page 1 of 1 | | | | APPLICANT(S): Mads HOLTEN-ANDERSEN et al. | | FILING DATE: April 10, 2000 | |
| | | | | GROUP ART UNIT: 1642 | | | |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|----|-----------------|------------|---------------|-------|----------|----------------|
| *EXAMINER INITIAL | 1. | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
| | | 20040157278 | 08-12-2004 | Astle, et al. | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|----|-----------------|------|---------|-----------------------|-------------------------|----|
| 1. | 2. | DOCUMENT NUMBER | DATE | COUNTRY | CLASS AND SUBCLASS | TRANSLATION PROVIDED | |
| | | | | | | Yes | No |
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| 1. | OTHER MATERIALS (Including Author, Title, Date, Pertinent Pages, Etc.) |
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| EXAMINER | DATE CONSIDERED |
|-----------------|------------------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FILING ACKNOWLEDGMENT
US PATENT AND TRADEMARK OFFICE

Mailing Date: 06/26/01 Attorney: KLB/jrc
Date Due: _____ Appln 09:546,573
File No.: 019829000310
Inventor(s): HOLTEN-ANDERSEN

Title: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1
(TIMP-1) AS A CANCER MARKER

Enclosures: Transmittal Form (Form PTO/SB/21); Supplemental Information Disclosure
Statement, Form PTO-1449 with copy of cited references; International
Search Report and Certified Copy of Priority Document; Certificate of First
Class Mailing and Return Mail Room Postcard (this one).

Please stamp the date of receipt of the enclosed documents and return this card to addressee.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231

On June 26, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: J.R. Clarke

J.R. Clarke

PATENT
Attorney Docket No.: 019829000310
Client Reference No.: 20236US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Holten-Andersen, Mads et al

Application No.: 09/546,573

Filed: April 10, 2000

For: TISSUE INHIBITOR OF MATRIX
METALLOPROTEINASES TYPE-1
(TIMP-1) AS A CANCER MARKER

Examiner: Rawlings, S.

Art Unit: 1642

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER 37
CFR §1.97 and §1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

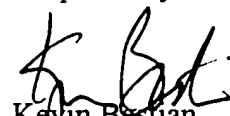
The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. Also enclosed is a copy of the Search/Examination report corresponding to the PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and

no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,


Kevin Bastian
Reg. No. 34,774

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
KLB:jrc

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|---|---|---------------|---|-------|-----------------------------|---------------------------------|
| FORM PTO-1449 (Modified) | | | Attorney Docket No.: 019829000310 | | Application No.: 09/546,573 | |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | | Applicant: Holten-Andersen, Mads et al. | | | |
| | | | Filing Date: April 10, 2000 | | Group: 1642 | |
| Reference Designation | | | U.S. PATENT DOCUMENTS | | | Page 1 |
| Examiner Initial | Document No. | Date | Name | Class | Sub-class | Filing Date (If Appropriate) |
| ____ AA | | | | | | |
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| FOREIGN PATENT DOCUMENTS | | | | | | |
| | Document No. | Date | Country | Class | Sub-class | Translation (Yes/No) |
| ____ AM | PA 1999 00476 | 09 April 1999 | Denmark | | | |
| ____ AN | | | | | | |
| ____ AO | | | | | | |
| ____ AP | | | | | | |
| ____ AQ | | | | | | |
| ____ AR | | | | | | |
| | | | | | | |
| OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | |
| ____ AS | International Search Report for International Application No. PCT/DK 00/0170 dated 10 August 2000 | | | | | |
| ____ AT | | | | | | |
| ____ AU | | | | | | |
| ____ AV | | | | | | |
| ____ AW | | | | | | |
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| EXAMINER | | | DATE CONSIDERED | | | |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT

☐ PROVISIONAL
☒ UTILITY

☐ DESIGN
☐ PCT

Application No.: 09/546,573

Date: JANUARY 2, 2004

Client/Matter No.: 59866.000002

Client: RIGHOSPITALET

Inventor(s): MADSEN HOLTEN-ANDERSEN ET AL.

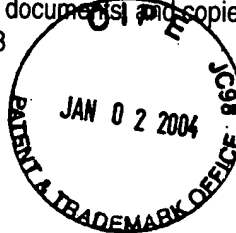
Atty/Sec.: SA/abs

Filing Date: April 10, 2000

Title: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1 (TIMP-1) AS A
CANCER MARKER

The following has been received in the U.S. Patent and Trademark
Office on the date stamped hereon:

- ☒ Second Supplemental Information Disclosure Statement
- ☒ Form PTO/SB/08A (1 pages) identifying 7 documents and copies of documents
- ☒ International Search Report Dated 9/24/03



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Patent Application of: |) | |
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| M. N. Holten-Andersen <i>et al.</i> |) | |
| |) | |
| Appln. No.: 09/546,573 |) | Art Unit: 1642 |
| |) | |
| Filed: April 10, 2000 |) | Examiner: S. L. Rawlings, Ph.D. |
| |) | |

For: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1
(TIMP-1) AS A CANCER MARKER

2nd SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith copies of the documents listed on the attached Form PTO/SB/08A (modified) for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

This 2nd Supplemental Information Disclosure Statement (IDS) is not to be construed as a representation that a search has, or has not, been conducted or that no better art exists. The filing of this 2nd Supplemental IDS is not to be construed as admission that the information cited in the IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Accordingly, Applicants respectfully request that the Examiner consider the documents cited on the PTO/SB/08A and that the Examiner indicate that the documents have been considered in this application by returning a copy of the Form PTO/SB/08A with the Examiner's initials in the left column per MPEP 609.

This 2nd Supplemental Information Disclosure Statement is filed prior to issuance of the first Office Action in this RCE application. Accordingly, no fees are due. If any fees are incurred upon the filing of this 2nd Supplemental Information Disclosure Statement, including any petition fees, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: January 2, 2004

By:


Stanislaus Aksman
Registration No. 28,562

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Facsimile: (202) 778-2201

SA/abs

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(use as many sheets as necessary)*

| | |
|----------------------|-------------------------------|
| Application Number | 09/546,573 |
| Filing Date | April 10, 2000 |
| First Named Inventor | M. N. HOLTEN-ANDERSEN et al., |
| Art Unit | 1642 |
| Examiner Name | S. L. Rawlings, Ph.D. |

| | | | | | |
|-------|---|----|---|------------------------|--------------|
| Sheet | 1 | of | 1 | Attorney Docket Number | 59866.000002 |
|-------|---|----|---|------------------------|--------------|

FOREIGN PATENT DOCUMENTS

| *Examiner Initial | Cite No. | FOREIGN PATENT DOCUMENT | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | TRANSLATION | |
|----------------------|-------------|----------------------------|----------------------------------|--------------------------------|--|---|-------------------------------------|--------------------------|
| | | Country Code: | Number - Kind Code (if known) | | | | YES | NO |
| | 1. | WO | 00/62070 | 10-19-2000 | Holten-Andersen et al. | | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
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NON-PATENT LITERATURE DOCUMENTS

| *Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | TRANSLATION | |
|-----------------------|-------------|--|-------------|----|
| | | | YES | NO |
| | 2. | HOLTEN-ANDERSEN, MADDS N. et al., "Plasma levels of Tissue Inhibitor of Metalloproteinases 1 measured during follow-up of colorectal cancer patients have clinical value in predicting patient outcome," Proceedings Of The American Association For Cancer Research Annual, Vol. 43, March 2002, page 715 (Abstract) | X | |
| | 3. | TAKADA, N. et al., "Postoperative sequential changes of serum levels of matrix metalloproteinase and tissue inhibitor of metalloproteinase in Japanese patients with the squamous cell carcinoma of esophagus," Proceedings Of The American Association For Cancer Research Annual, Vol. 40, March 1999, page 346 (Abstract) | X | |
| | 4. | ZUCKER, STANLEY et al., "Plasma assay of gelatinase B: Tissue inhibitor of metalloproteinase complexes in cancer," Cancer (Philadelphia), Vol. 76, No. 4, 1995, pages 700-708 | X | |
| | 5. | HOLTEN-ANDERSEN, MADDS N. et al., "Total levels of tissue inhibitor of metalloproteinases 1 in plasma yield high diagnostic sensitivity and specificity on patients with colon cancer," Clinical Cancer Research: An Official Journal Of The American Association For Cancer Research, Vol. 8, No. 1, January 2002, pp. 156-164 | X | |
| | 6. | ZHOU, W. et al., "Identifying markers for pancreatic cancer by gene expression analysis," Database Medline [Online], Abstract of Cancer Epidemiology, Biomarkers & Prevention: A Publication Of The American Association For Cancer Research, Cosponsored by The American Society Of Preventive Oncology, 2/1998, Vol. 7, No. 2, 2 pages, (Abstract) | X | |
| | 7. | International Search Report for Application No. PCT/DK03/00230, mailed September 24, 2003 | X | |

EXAMINER SIGNATURE

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

UTILITY ☒

DESIGN ☐

Application Serial No.: 09/546,573

Client/Matter: 59866.000002

Inventor: M. N. Holten-Andersen et al.

Client: Righospitalet

Filing Date: April 10, 2000

Atty/Sec.: SA/sdw

Date: August 21, 2001

Title: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES
TYPE-1 (TIMP-1) AS A CANCER MARKER

The following has been received in the U.S. Patent and Trademark Office
on the date stamped hereon:

1. *Supplemental Information Disclosure Statement*
2. *Form PTO/SB/08A*



09/546,573

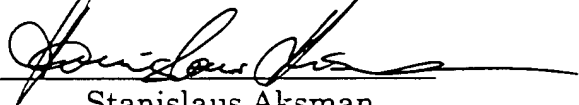
in this application by returning a copy of the Form PTO/SB/08A with the Examiner's initials in the left column per MPEP 609.

Applicants respectfully point out that the submission of the references is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of the June 26th IDS or Supplemental IDS is not an indication that a search has been made.

This Supplemental IDS is submitted prior to the issuance of a first Office Action on the merits; therefore, it is believed that no fees are required in connection therewith. If any fees are necessitated by the filing of this Information Disclosure Statement, please charge the undersigned's Deposit Account No. 50-0206.

Date: August 20, 2001

Respectfully submitted,
HUNTON & WILLIAMS


Stanislaus Aksman
Registration No. 28,562

1900 K Street, N.W., Suite 1200
Washington, D.C. 20006-1109
Ph. (202) 955-1500
Fax (202) 778-2201

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-CO)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

| | |
|------------------------|-----------------------------|
| Application Number | 09/546,573 |
| Filing Date | 04-10-2000 |
| First Named Inventor | Mads Holten-Andersen et al. |
| Group Art Unit | 1642 |
| Examiner Name | S. Rawlings |
| Attorney Docket Number | 59866.000002 |

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|------------------------|--------------------------|----------------------|--------------------------------------|--|--|---|
| | | Number | Kind Code ² (if known) | | | |
| | U1 | 5,324,634 | | Zucker | 06-28-1994 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ₄ |
|------------------------|--------------------------|-------------------------|---------------------|--------------------------------------|---|--|--|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | F1 | | 9738314 | WO | Miller et al. | 10-16-1997 | | |

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | P1 | National Library of Medicine, PubMed Website, "Serum levels of a tissue inhibitor of metalloproteinases-1 (TIMP-1) in bladder cancer patients", Naruo S et al., Int J Urol, Vol. 1, No. 3 September 1994, pp. 238-231, see abstract | |
| | P2 | National Library of Medicine, PubMed Website, "Tissue inhibitors of metalloproteinases (TIMP) in invasion and proliferation", Henriet P. et al., APMIS, Vol. 109, No. 1, January 1999, pp. 111-119, see abstract | |
| | P3 | Patent Abstracts of Japan, JP8136548 A, Morinaga, 05-31-1996 | |
| | P4 | Dialog Information Services, File 159, Cancerlit, accession no. 93691448, Guillem JG et al., "Evaluation of tissue inhibitor of metalloproteinase-1 (TIMP-1) as a prognostic marker of human colorectal cancer invasion", Proc Annu Meet Am Assoc Cancer Res; 34:A466 1993 | |
| | P5 | Dialog Information Services, File 159, Cancerlit, accession no. 96647008, "Elevated tissue inhibitor of metalloproteinase 1 RNA in colorectal cancer stroma correlates with lymph node and distant metastases" Clin Cancer Res; 1(8): 899-906 1995 Zeng Z et al. | |

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: S. L. Rawlings, Ph.D.

For: **TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES
TYPE-1 (TIMP-1) AS A CANCER MARKER**

INFORMATION DISCLOSURE STATEMENT

Sir:

Accordingly, Applicant respectfully requests that the Examiner consider the references cited on the PTO/SB/08A and that the Examiner indicate that the references have been considered in this application by returning a copy of the Form PTO/SB/08A with the Examiner's initials in the left column per MPEP 609.

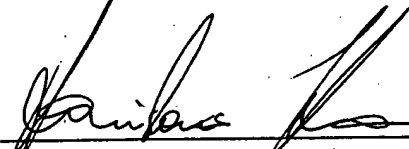
This Information Disclosure Statement is being submitted after the mailing of a final Office Action. Pursuant to 37 C.F.R. § 1.97(d)(2), a check in the amount of \$180.00 as set forth in § 1.17(p) is enclosed. In the event any variance exists between the amount enclosed and the Patent Office charges, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: July 10, 2003

By:


Stanislaus Aksman
Registration No. 28,562

HUNTON & WILLIAMS LLP
1900 K Street, N.W.
Suite 1200
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number 09/546,573

Filing Date April 10, 2000

First Named Inventor Mads N. Holten-Andersen

Art Unit 1642

Examiner Name S. Rawlings

Sheet 1 of 1

Attorney Docket Number 59866.000002

NON-PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | TRANSLATION | |
|----------------------|-------------|--|-------------|----|
| | | | YES | NO |
| | 1. | Mads N. Holten-Andersen et al., "Measurement of the Noncomplexed Free Fraction of Tissue Inhibitor of Metalloproteinases I in Plasma by Immunoassay", <i>Clinical Chemistry</i> 48:8, 1305-1313 (2002) | | |
| | 2. | Mads N. Holten-Andersen et al., "Total Levels of Tissue Inhibitor of Metalloproteinases 1 in Plasma Yield High Diagnostic Sensitivity and Specificity in Patients with Colon Cancer", <i>Clinical Cancer Research</i> , Vol. 8, 156-164, January 2002 | | |
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EXAMINER SIGNATURE

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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PATENT

☐ **PROVISIONAL**
☒ **UTILITY**

☐ **DESIGN**
☐ **PCT**

Application No.: 09/546,573 Date: July 30, 2003
Client/Matter No.: 59866.000002 Client: RIGHOSPITALET
Inventor(s): M. N. Holten-Andersen et al. Atty/Sec.: SA/jt
Title: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1 (TIMP-1)
AS A CANCER MARKER

The following has been received in the U.S. Patent and Trademark
Office on the date stamped hereon:

- ☒ RCE Transmittal Form
- ☒ Supplemental Information Disclosure Statement
- ☒ Form PTO/SB/08A with Copies of 12 References
- ☒ Check No. 2057148 in the Amount of \$375.00



DOCKETED

7-31-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Patent Application of: |) | |
| |) | |
| M. N. Holten-Andersen et al. |) | |
| |) | |
| Appl. No.: 09/546,573 |) | Art Unit: 1642 |
| |) | |
| Filed: April 10, 2000 |) | Examiner: S. L. Rawlings, Ph.D. |
| |) | |

For: TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES
TYPE-1 (TIMP-1) AS A CANCER MARKER

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicant respectfully requests consideration of the references listed on the attached Form PTO/SB/08A (modified). Copies of the references listed are also enclosed.

This Information Disclosure Statement (IDS) is not to be construed as a representation that a search has, or has not, been conducted or that no better art exists. The filing of this IDS is not to be construed as admission that the information cited in the IDS is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

Accordingly, Applicant respectfully requests that the Examiner consider the references cited on the PTO/SB/08A and that the Examiner indicate that the references have been considered in this application by returning a copy of the Form PTO/SB/08A with the Examiner's initials in the left column per MPEP 609.

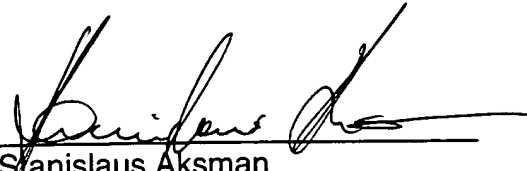
It is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Date: July 30, 2003

By:


Stanislaus Aksman
Registration No. 28,562

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1900 K Street, N.W.
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Telephone: (202) 955-1500
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|--|---|-----------|---|-------------------------------|--|-------------------------|--|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | | | Application Number | | 09/546,573 | |
| | | | | Filing Date | | April 10, 2000 | |
| | | | | First Named Inventor | | Mads N. Holten-Andersen | |
| | | | | Art Unit | | 1642 | |
| | | | | Examiner Name | | S. Rawlings | |
| Sheet | 1 | of | 1 | Attorney Docket Number | | 59866.000002 | |

NON-PATENT LITERATURE DOCUMENTS

| *Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | TRANSLATION | |
|--------------------|----------|--|-------------|----|
| | | | YES | NO |
| | 1. | Mads N. Holten-Andersen et al., "Measurement of the Noncomplexed Free Fraction of Tissue Inhibitor of Metalloproteinases I in Plasma by Immunoassay", <i>Clinical Chemistry</i> 48:8, 1305-1313 (2002) | | |
| | 2. | Mads N. Holten-Andersen et al., "Total Levels of Tissue Inhibitor of Metalloproteinases 1 in Plasma Yield High Diagnostic Sensitivity and Specificity in Patients with Colon Cancer", <i>Clinical Cancer Research</i> , Vol. 8, 156-164, January 2002 | | |
| | 3. | Standard Search Report, in connection with application No. 32127 DK 01, 8 April 2002, Denmark (9 references) | | |
| | 4. | Zhou, et al., "Identifying Markers for Pancreatic Cancer by Gene Expression Analysis," <i>Cancer Epidemiology, Biomarkers & Prevention</i> , (1998), 7(2), 109-112. | | |
| | 5. | Wood, et al., "In Situ Hybridization Studies Of Metalloproteinases 2 And 9 And TIMP-1 And TIMP-2 Expression In Human Prostate Cancer," <i>Clinical & Experimental Metastasis</i> (1997), 15(3), 246-258. | | |
| | 6. | Jung, et al., "Quantification Of Matrix Metalloproteinases And Tissue Inhibitors Of Metalloproteinase In Prostatic Tissue: Analytical Aspects", <i>Prostate</i> , (1998), 34(2), 130-136, New York. | | |
| | 7. | Naruo, et al., "Serum Levels of a Tissue Inhibitor of Metalloproteinases-1 (TIMP-1) in Bladder Cancer Patients", <i>International Journal of Urology</i> , Churchill Livingstone, Tokyo, JP, vol. 1, no. 3, September 1994. | | |
| | 8. | Zucker, et al., "Plasma Assay of Gelatinase B: Tissue Inhibitor of Metalloproteinase Complexes in Cancer," <i>Cancer</i> , American Cancer Society, Philadelphia, PA, vol. 76, no. 9, August 15, 1995. | | |
| | 9. | Henriet, et al., "Tissue Inhibitors of Metalloproteinases (TIMP) in Invasion and Proliferation", <i>APMIS</i> , Copenhagen, DK, vol. 107, no. 1, 1999. | | |

FOREIGN PATENT DOCUMENTS

| *Examiner Initial | Cite No. | FOREIGN PATENT DOCUMENT | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | TRANSLATION | |
|-------------------|----------|-------------------------|-------------------------------|--------------------------------|---|---|--------------------------|--------------------------|
| | | Country Code: | Number - Kind Code (if known) | | | | YES | NO |
| | 10. | WO | 00/62070 A | 10-19-2000 | Holten-Andersen et al. | | <input type="checkbox"/> | <input type="checkbox"/> |
| | 11. | WO | 00/20860 A | 04-13-2000 | Calbiochem Novabiochem Corp. | | <input type="checkbox"/> | <input type="checkbox"/> |
| | 12. | WO | 93/20447 A | 10-14-1993 | The Research Foundation of State University of New York | | <input type="checkbox"/> | <input type="checkbox"/> |

EXAMINER SIGNATURE

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TO THE U.S. PATENT AND TRADEMARK OFFICE

Please stamp the date of receipt of the following document(s) and return this card to us:

| | |
|--------------------------|---|
| INVENTOR(S): | HOLTEN-ANDE, N, Mads et al. |
| RE: | TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES TYPE-1 (TIMP-1) AS A CANCER MARKER |
| TITLE OF DOCUMENT(S): | PTO/SB/21 Transmittal Form; Information Disclosure Statement, Form PTO-1449, photocopy of 35 references cited and Certificate of First Class Mailing. |
| Application No. | 09/546,573 |
| File No. | 019829000310 |
| Date Due | |
| Date Mailed | March 27, 2001 |
| Attorney/Secretary | Kevin Bastian/Jill Clarke |

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

PATENT
Attorney Docket No.: 18484-002130US

Assistant Commissioner for Patents
Washington, D.C. 20231

On March 27, 2001

TOWNSEND and TOWNSEND and CREW LLP

By: Jill R. Clarke
Jill R. Clarke

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HOLTEN-ANDERSEN, Mads

Application No.: 09/546,573

Filed: April 10, 2000

For: TISSUE INHIBITOR OF MATRIX
METALLOPROTEINASES TYPE-1 (TIMP-1)
AS A CANCER MARKER

Examiner: Unassigned

Art Unit: 1643

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:


The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and

no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicants believe that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,


Kevin L. Bastian
Reg. No. 34,774

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Two Embarcadero Center, 8th Floor
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KLB/jrc

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|---|--|-----------------------------------|---------|-----------------------------|-----------|---------------------------------|
| FORM PTO-1449 (Modified) | | Attorney Docket No.: 019829000310 | | Application No.: 09/546,573 | | |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | Applicant: HOLTEN-ANDERSEN, Mads | | | | |
| | | Filing Date: April 10, 2000 | | Group: 1643 | | |
| Reference Designation | | U.S. PATENT DOCUMENTS | | | | Page 1 |
| Examiner Initial | Document No. | Date | Name | Class | Sub-class | Filing Date (If Appropriate) |
| AA | 5,324,634 | 06/28/94 | Zucker | 435 | 7.23 | |
| | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | |
| | Document No. | Date | Country | Class | Sub-class | Translation (Yes/No) |
| AB | | | | | | |
| | | | | | | |
| OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | |
| AC | Baker et al., "Serum Metalloproteinases and their Inhibitors: Markers for Malignant Potential," <i>Br. J. Cancer</i> 70:506-512 (1994) | | | | | |
| AD | Birkedal-Hansen et al., "Matrix Metalloproteinases: A Review," <i>Critical Reviews in Oral Biology and Medicine</i> 4:197-250 (1993) | | | | | |
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| AP | Keyszer et al., "Circulating Levels of Matrix Metalloproteinases MMP-3 and MMP-1, Tissue Inhibitor of Metalloproteinases 1 (TIMP-1), and MMP-1/TIMP-1 Complex in Rheumatic Disease. Correlation with Clinical Activity of Rheumatoid Arthritis versus Other Surrogate Markers," <i>The Journal of Rheumatology</i> 26:251-258 (1999) | | | | | |
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|---|---|-----------------------------------|-----------------------------|
| FORM PTO-1449 (Modified) | | Attorney Docket No.: 019829000310 | Application No.: 09/546,573 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) | | Applicant: HOLTEN-ANDERSEN, Mads | |
| | | Filing Date: April 10, 2000 | Group: 1643 |
| _____ AS | Khokha et al., "Suppression of Invasion by Inducible Expression of Tissue Inhibitor of Metalloproteinase-1 (TIMP-1) in B16-F10 Melanoma Cells," <i>Journal of the National Cancer Institute</i> 84:1017-1021 (1992) | | |
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| _____ BF | Stetler-Stevenson et al., "Extracellular matrix 6: Role of matrix metalloproteinases in tumor invasion and metastasis," <i>The FASEB Journal</i> 7:1434-1441 (1993) | | |
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| EXAMINER | | | |
| DATE CONSIDERED | | | |

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